ALLERGAN

2525 Dupont Drive, P.O. Box 19534, Irvine, California, USA 92623-9534 Telephone: (714) 246-4500 Website: www.allergan.com

FEB 1 1 2002

510(k) SUMMARY
COMPLETE® brand Multi-Purpose Solution

K013479

This summary uses the format provided in 21 CFR 807.92:

(a)(1) **Submitter:**

Paul J. Nowacki
Manager
Regulatory Affairs
Allergan
2525 Dupont Drive
Irvine CA 92612

Phone: (714) 246-6761
Fax: (714) 246-4272

Summary Prepared: October 2001

(a)(2) **Device Trade Name:** COMPLETE® brand Multi-Purpose Solution

Device Common Name: Soft (Hydrophilic) Contact Lens Solution

Device Classification Names: Accessories to Contact Lens Solution (86LPN)

(a)(3) **Identification of Predicate Device:** Whether used with frequent replacement or conventional lenses (those replaced at intervals of 90 days or longer), the modified COMPLETE® brand Multi-Purpose Solution care regimen is substantially equivalent to the approved COMPLETE® brand Multi-Purpose Solution care regimen.

(a)(4) **Device Description:** There are no formulation or other changes in the device description.

(a)(5) **Intended Use (Indications for Use):** COMPLETE® brand Multi-Purpose Solution is indicated for the care of soft (hydrophilic) contact lenses. Use this product, as recommended by your eye care practitioner, to:

- Chemically (NOT HEAT) Disinfect
- Clean
- Rinse
- Store
- Remove Protein
- Condition

(a)(6) **Comparison of Technological Characteristics:** There are modified cleaning instructions for all soft contact lenses but there are no changes to the product formulation or other technological characteristics.

(b)(1) **Discussion of Nonclinical:**

Microbiological Studies: We evaluated disinfection efficacy using methods outlined in FDA's May 1, 1997, Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products. COMPLETE® brand Multi-Purpose Solution meets FDA requirements for disinfection of contact lenses when used with the modified cleaning regimen. The product also meets USP Modified criteria for Preservative Effectiveness Testing and USP Sterility test requirements as shown by previous testing.

Toxicological Studies: Toxicological studies were included in 510(k) K003252 for frequent replacement lenses, on October 16, 2000.

(b)(2) **Discussion of Clinical Data:**

Nine investigators enrolled 157 subjects who replace hydrogel contact lenses at intervals of three months or longer (conventional wear) in a three-month, parallel group study. Subjects received new lenses and were randomized to use COMPLETE® in either the standard (rub, rinse, soak, optional rinse) regimen or a modified (rinse, soak, mandatory rinse) regimen. One-hundred and fifty-one subjects completed the study with three subjects withdrawing from each regimen.

The primary acceptability variable was mean change from baseline in lens comfort score. The modified regimen group was demonstrated to be non-inferior to the standard regimen by constructing 95% confidence intervals around the mean changes from baseline in lens comfort at Day 90.

Acceptability Results: There was no statistically significant difference between the two regimens in:

- Mean lens comfort score at baseline or at any follow-up visit
- Symptoms of discomfort
- Maximum severity grade of any symptom of discomfort
- Number of subject visits with clinically significant symptoms of discomfort (all causes).
- Change from baseline for burning and stinging, blurry vision, unusual eye secretion, excessive tearing, itching, increased lens awareness, redness, or light sensitivity
- Overall subjective vision quality
- Mean lens wearing time
- Average daily lens wearing time change from baseline
- Number of Type II or Type IV lenses analyzed at the final study visit
- Subject ratings of the contact lens solution used, comfort rating, and vision quality.

(b)(2) **Discussion of Clinical Data (Continued):**

Safety Results: No subject in either regimen experienced an unanticipated adverse device effect or a sight-threatening event, iritis, infiltrate, ulcer, ocular infection, or two-grade change in neovascularization.

There were no statistically significant differences between the two regimens in:

- Worst severity of subject eyes at each visit for the slit lamp examination findings of edema, corneal neovascularization, bulbar hyperemia, palpebral conjunctival observations, or other complications
- Maximum severity grade of any slit lamp examination finding
- Severity at baseline and the worst change from baseline in any slit lamp parameter
- Number of subjects with clinically significant slit lamp examination findings
- Number of visits with clinically significant slit lamp examination findings
- Change from baseline in study lens-corrected visual acuity
- Number of eyes discontinued from the study, in the average wear time of lenses, or in the number of missed visits.

Cleaning Effectiveness: Lenses from the clinical study were returned to Allergan and examined in the laboratory for surface deposits and general cleanliness. Results show that COMPLETE® brand Multi-Purpose Solution used with the modified regimen is equivalent to the standard regimen and is an effective cleaner for soft (hydrophilic) contact lenses.

Conclusion: COMPLETE® brand Multi-Purpose Solution used with a modified regimen has an acceptable safety profile and is as effective as COMPLETE® Multi-Purpose Solution used with a standard regimen among hydrogel contact lens wearers who replace their lenses on a conventional replacement schedule of three months or longer.

(b)(3) **Conclusions Drawn from Data Supporting Equivalence Determination:** We conclude that the safety, efficacy and acceptability of COMPLETE® brand Multi-Purpose Solution, when used with the modified regimen, is substantially equivalent to COMPLETE® brand Multi-Purpose Solution used with the standard regimen and other multipurpose solutions currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 1 2002

Allergan, Inc.
C/O Paul J. Nowacki
Manager, Regulatory Affairs
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92623-9534

Re: K013479
Trade/Device Name: COMPLETE® brand Multi-Purpose Solution (Modified lens care directions)
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LPN
Dated: December 19, 2001
Received: December 20, 2001

Dear Mr. Nowacki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) NUMBER:
(IF KNOWN): K013479

DEVICE NAME: COMPLETE® brand Multi-Purpose Solution

INDICATIONS FOR USE:

COMPLETE® brand Multi-Purpose Solution is indicated for the care of soft (hydrophilic) contact lenses. Use this product, as recommended by your eye care practitioner, to:

- Chemically (NOT HEAT) Disinfect
- Clean
- Rinse
- Store
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- Condition

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use ✓
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Karen Whitbeck
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

K013479